

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application of: **Khanapure et al**

Application No.: **Not Yet Assigned**

Filed: **HEREWITH**

For: **Substituted Aryl Compounds as Novel Cyclooxygenase-2 Selective Inhibitors,  
Compositions and Methods of Use**

Docket No: 102258.124 US2

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicants bring to the attention of the Examiner the documents listed on the attached PTO-1449 Form.

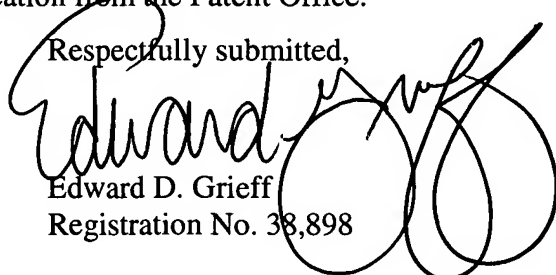
A copy of each of the cited references is not submitted herewith since they were filed and/or cited in one of the applications to which the present application claims priority. 37 CFR § 1.98(d).

The submission of this Information Disclosure Statement does not represent that a search has been made and does not constitute an admission that the listed documents are material to patentability or that the listed documents are prior art.

This Information Disclosure Statement is being submitted before the mailing date of a first office action on the merits or a notice of allowance. Accordingly, no fee is due.

Applicants respectfully request that the Examiner initial and return a copy of the enclosed PTO-1449 Form with the next communication from the Patent Office.

Respectfully submitted,

  
Edward D. Grieff  
Registration No. 38,898

Date: December 10, 2003  
HALE AND DORR LLP  
1455 Pennsylvania Avenue, NW  
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PTO/SB/08A (08-00)  
Approved for use through 10/31/2002. OMB 0651-0031  
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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>		<b>Complete if Known</b>	
	Application Number	10/024,046	
	Filing Date	December 21, 2001	
	First Named Inventor	Khanapure	
	Group Art Unit		
	Examiner Name		
Sheet	1	of	9
	Attorney Docket Number	102258.124 US1	

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		5,281,613		Bradbury et al	01-25-1994	
		5,387,592		Bradbury et al	02-07-1995	
		5,463,135		Kanschik-Conradsen et al	10-31-1995	
		5,567,711		Sheppard et al	10-22-1996	
		5,593,994		Batt et al	01-14-1997	
		5,621,000		Arena et al	04-15-1997	
		5,643,922		Sheppard et al	07-01-1997	
		5,654,305		Sheppard et al	08-05-1997	
		5,700,947		Soldato	12-23-1997	
		5,703,073		Garvey et al	12-30-1997	
		5,710,159		Voss et al	01-20-1998	
		5,719,164		Weidmann et al	02-17-1998	
		5,726,305		Weidmann et al	03-10-1998	
		5,780,495		Del Soldato	07-14-1998	
		5,861,426		Del Soldato et al	01-19-1999	
		5,932,586		Batt et al	08-03-1999	
		5,990,148		Isakson et al	11-23-1999	
		6,010,981		Siddall et al	01-04-2000	
		6,040,341		Del Soldato et al	03-21-2000	
		6,043,232		Garvey et al	03-28-2000	

FOREIGN PATENT DOCUMENTS								
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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		WO	94/04484		Matji et al	03-03-1994		
		JP	6-107646		Takashi et al	04-19-1994		
		WO	94/12463		Arena	06-09-1994		
		WO	95/01426		Schneider et al	01-12-1995		
		WO	95/09831		Del Soldato	04-13-1995		
		WO	95/30641		Del Soldato et al	11-16-1995		
		WO	96/10012		Batt et al	04-04-1996		
		WO	96/26921		Chaki et al	09-06-1996		
		WO	96/32946		Garvey et al	10-24-1996		
		WO	97/31654		Del Soldato	09-04-1997		

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		6,043,233		Garvey et al	03-28-2000	
		6,046,217		Friesen et al	04-04-2000	
		6,048,858		Garvey et al	04-11-2000	
		6,051,588		Garvey et al	04-18-2000	
		6,057,347		Garvey et al	05-02-2000	
		6,083,515		Garvey et al	07-04-2000	
		6,143,734		Garvey et al	11-07-2000	
		6,232,315	B1	Shafer at al	05-15-2001	
		6,245,797	B1	Winokur	06-12-2001	
		6,248,745	B1	Hamley et al	06-19-2001	
		6,297,260	B1	Bandarage et al	10-02-2001	
		6,323,234	B1	Garvey et al	11-27-2001	

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		WO	98/09948		Del Soldato et al	03-12-1998		
		WO	98/26127		Freudenreich et al	06-18-1998		
		WO	98/56899		Hage et al	12-17-1998		
		WO	98/57633		Kajiji	12-23-1998		
		WO	99/14194		Friesen et al	03-25-1999		
		WO	99/14195		Freisen et al	03-25-1999		
		WO	99/20110		Winokur	04-29-1999		
		WO	99/21859		Cheung et al	05-06-1999		
		WO	99/34054		Damhus et al	07-08-1999		
		WO	99/44595		Del Soldato	09-10-1999		

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		WO	99/45004		Del Soldato	09-10-1999		
		WO	99/45913		Nichtberger	09-16-1999		
		WO	99/58635		Josa et al	11-18-1999		
		WO	00/05225		Bottcher et al	02-03-2000		
		WO	00/06585		Del Soldato	02-10-2000		
		WO	00/18352		Shafer et al	04-06-2000		
		WO	00/25776		Bandarage et al	05-11-2000		
		WO	00/44705		Del Soldato et al	08-03-2000		
		WO	00/51988		Benedini et al	08-03-2000		
		WO	00/61537		Del Soldato	10-19-2000		

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**Complete if Known**

Application Number	10/024,026
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		WO	00/61541		Del Soldato	10-19-2000		
		WO	00/61549		Del Soldato	10-19-2000		
		WO	00/61604		Del Soldato	10-19-2000		
		EP	1 052 238	A1	Tanimoto et al	11-15-2000		
		WO	00/72838	A1	Eek et al	12-07-2000		
		WO	00/73278	A2	Boes et al	12-07-2000		
		WO	01/00563	A1	Benedini et al	01-04-2001		
		WO	01/04082	A1	Castaldi et al	01-18-2001		
		WO	01/10814	A1	Benedini et al	02-15-2001		
		WO	01/12584	A2	Del Soldato	02-22-2001		

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Sheet	5	of	9
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# **Notice of References Cited**

Sheet 7 of 9

Application/Control No.

10/024,046

Applicant(s)/Patent Under Reexam

Subhash P. Khanpure et al

Examiner

Sudhaker Patel

Art Unit

1624

## **U.S. PATENT DOCUMENTS**

* A	Document Number Country Code-Number-Kind Code	Date MM-YYYY <sup>1</sup>	Name	Classification <sup>2</sup>
B				
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## **FOREIGN PATENT DOCUMENTS**

* X	Document Number Country Code-Number-Kind Code	Date MM-YYYY <sup>1</sup>	Country	Name	Classification <sup>2</sup>
N	9,610,012	4/1996	WO	Batt et al	— —
O	9,626,921	9/1996	WO	Asamura et al	— —
P					
Q					
R					
S					
T					

## **NON-PATENT DOCUMENTS**

* U	Include, as applicable: Author, Title, Date, Publisher, Edition or Volume, Pertinent Pages
	Nathan "NO as a secretory product of mammalian cells", FASEB J. 6, 3052-3064 (1992).
V	Schlosser et al, "COX-2 is Overexpressed..."; PubMed: 12131767; Pancreas, 25/1, 26-30 (2002).
W	Slomiany et al, "Activn....COX and NOS during ...ulcer healing", PubMed; J. Physiol. Pharmacol, 53/2, 159-69 (2002).
X	Rajnakova et al, "Expression of NOS, COx-2 and p53...gastric cancer", PubMed: 11566494; Cancer Lett, 172/2, 177-85 (2001).

\* A copy of this reference is not being furnished with this Office action. See MPEP § 707.05(a).

<sup>1</sup> Dates in MM-YYYY format are publication dates.

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Q					
R					
S					
T					

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U	Devaux et al,"Lipopolysaccharide-induced...E2 mediated...NOS activn...Cox-2 ...";PuBMed;J.Immun.,167/7,3962(2001).
V	McCarthy et al,"Prev. and Treatment of gastroint. and complicn. due to NSAIDs",PuBMed:11566039;Best Pract. res.Clin Gast.,15/5,755(2001).
W	Ahmad et al,"Renal failure....celecoxib and rofecoxib",PuBMed:12093311;Drug Saf,25/7,537-44(2002).
X	Dicjens et al,"COX-2 Expres. in Padiatric Sarcomas",PuBMed:12024286;Pediater Dev Pathol,5/4(2002).

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P					
Q					
R					
S					
T					

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U	Cutsem et al, "The treatm....adv.colorectal cancer....", puBMed:11969241; Best Pract.res Clin Gastr., 16/2, 319(2002).
V	Khanna et al, "Selective COX-2 inhibitors: heteroaryl modif....diarylimidazoles are potent, orally active antiinflam....", PuBMed:10956225; J.Med.Chem. 43/16, 3168(2000).
W	
X	

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